



Data-Driven Decisions for Planning and Budgeting Research Protocols

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Where do protocols come from?

- Sources of research protocols

- **Government**

- Local, State, Federal

- Industry

- Request for Proposals

- Collaborator-Initiated Investigations

- Internal, External



There are numerous entities across the government sector that serve as a source of new research protocols. As an academic teaching hospital with an established research presence, government funded research makes up a large portion of our institutions research portfolio.

When partnering with a given agency, it is typical that you will have to supply unique information describing the population of interest and recruitment methods in detail.



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Similarly, there are many industry sponsors of research that are always looking for partners in order to access specific patient populations or target various research subjects. I have listed a handful that my research group has partnered with over the past years.

These groups typically want very clear and detailed information regarding the subject population, as they are usually seeking to partner with those hospitals/care centers that will help them answer a specific question by targeting a defined group of patients/subjects (reduce variability, bias, confounding, etc.).



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There are also many private funding agencies that release requests for proposals and each of these will have their own requirements in terms of outlining the specifics of your research protocol.



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 - Internal, External

Merchant-Borna, Kian

From:
Sent: Monday, June 02, 2014 5:25 PM
To: Bazarian, Jeff
Cc: Merchant-Borna, Kian
Subject: RE: Pupilometry study

Hi Jeff and Kian,

Just following up on a couple of things related to our possible collaboration on the Pupilometry study. We have a meeting with our research team here on Wednesday, and I have a couple of questions.

1. You mentioned that there may be a cost to cover the ED research folks at Strong. Do you have an estimate of what that might be?

2. The current age range for subjects is 16-60. We have discussed possibly lowering the age to 12, but it's probably not appropriate to analyze subjects that young in the same sample as adults. Kian, I think you were going to check to see what the expected recruitment rate might be if we kept the age as is, which would help determine if we need to change it.

Finally, collaborator-initiated investigations, either internal or external, are yet another source of potential research protocols.

As an example, I received the displayed email just this week in regard to a research protocol by one of our collaborators Syracuse University.

The inquiry was a direct response to low recruitment rates at his site.



Where do protocols come from?

- Sources of research protocols
 - What's the point?
- Be cognizant of the funding entity and the relationship you have with them

Why am I telling you this? The point I want you take away is that each and every one of us have unique challenges before a trial even begins. Knowing who your sponsor, “client” or funding source is, is an important piece of information that will help you take a more direct course of action and become more informed and efficient in your responsibilities. Ultimately, it is important to consider the sponsor because this will give you a sense of how much and where you will have flexibility moving forward.



Evaluating Potential Protocols and Future Studies

- Perform a feasibility analysis
 - Obtain site-specific numbers for sub-population of interest
 - Do you have access to the population of interest?
 - How do you know?
 - Identify major barriers or obstacles to enrollment
 - Environment, timing, data/sample collection, etc.
 - Consider the expenses involved
 - Personnel, duration, resources, etc.



Moving a few steps forward; after you've considered whether or not you want to take on the project, you need to answer the question of whether or not you can complete the protocol.

I generally start with the low-hanging fruit that are the greatest threats to the protocols success. For example, will I need to recruit 100 Alaskan natives in Rochester, NY? This probably won't work. If you cannot access the population of interest how will you conduct the protocol? Stop, think, and consider the operations and logistics involved in executing the study. Perhaps the protocol requires all 100 individuals be recruited in one week? Maybe it's just too expensive to drive to make home visits to rural areas? Consider these factors, and how you'll move forward with the resources available.



Evaluating Potential Protocols and Future Studies

- Assess the potential study
 - Compare enrollment parameters described in protocol against historical data
 - Evaluate the *context* of subject enrollment
 - Timeframe and constraints for recruitment
 - Available tools and resources
 - Estimated costs associated with enrollment



* I'll describe in a moment sources of historical data, but it will be important to consider this when comparing to potential recruitment efforts. * This past fall, I managed a protocol that required my staff to pull and evaluate football players following an impact to head as measured by sensors installed in their helmets. When I originally read through the protocol, it seemed quite simple in nature. .. However, the operationalization of these activities was a far greater challenge than I ever imagined, as it was a very disruptive event for the coaching staff, the players, and the athletic trainers. I quickly realized we needed to adapt our strategies in order to continue.



Using Data to Reasonably Predict Outcome

- **Methods used to predict enrollment**

- Determine which data to collect
- Identify databases and fields of data
- Case example

chief complaint \neq reason for visit \neq discharge diagnosis \neq ICD-9

- **Sources of variation or discrepancy**

- Explore the sources used for prediction
- Understand the reasons behind any differences
- Reconciliation



What are ways that you can reliably predict enrollment rates? When considering trends and historical data, it is important to consider what sources of data you obtain information from. First, you need to consider what it is that you want to know, which will help you to determine which data you will want to collect. Consider where you might find this information, which will point you towards the appropriate sources of data. The image on the screen was taken from the URMC intranet page for providers. Each of these is a source of information that will provide specific data describing the behavior and events in our clinical care system.

Once you identify a database that may contain the information you are looking for, consider what data fields you want to evaluate to best answer the question at hand. For example, in eRecord, I can generate a report between two time points that may include these 4 variables. For some individuals, these will be the same, and for others very different. Consider what exactly it is that you need, and consider only this information if it answers your question. These differences may also be used to explain sources of variation between what you predicted prior to initiating the research and your observed enrollment rates.

The sooner you can understand the reasons behind these differences, the soon you will be able to use them to your advantage. For example, strategic and creative applications of available data can be used to manipulate protocol processes that may involve staffing. Consider the daily variation in the availability of patients to enroll into a given protocol. I recently managed a randomized, placebo-controlled drug trial protocol where patients with neck pain due to an MVC were enrolled to and treated with Venlafaxin. Given the sensitive issues relating to enrolling subjects into a drug trial, the enrollment process took quite a bit of time for study staff. Given that MVC's increased during peak travel times (AM/PM rush hour), the number of missed enrollments during these times increased, making it immediately apparent that a change in staffing was warranted. By carefully examining the enrollment numbers as a % of overall MVCs by day and by hour while holding the number of staff constant, it became clear that a change in the available staff needed to be increased during these periods of greater influx.



Collecting Specific Metrics for Specific Decisions

- **Example:** Imaging records

- A physician requests two imaging orders for a patient
 - one for chest, another for abdomen



- **eRecord:** each order is recorded as a distinct record
- **Imagecast:** there is only one 'study' for the batch of orders

- **Example:** Patient visits by procedure type

- A patient who has a complicated visit receives 3 EKG's
 - You are curious to know how many different patients receive an EKG during their visit
- **Epic/Hyperspace:** each order is recorded within a distinct record
- **Flowcast:** each order is recorded as a distinct visit (e.g. 3 visits, not 1)

Here are two examples that I have had the unfortunate first hand experience of going down the wrong road thinking I was well informed.

Epic/Hyperspace; each procedure is wrapped up under a single visit, or contact serial number (CSN)

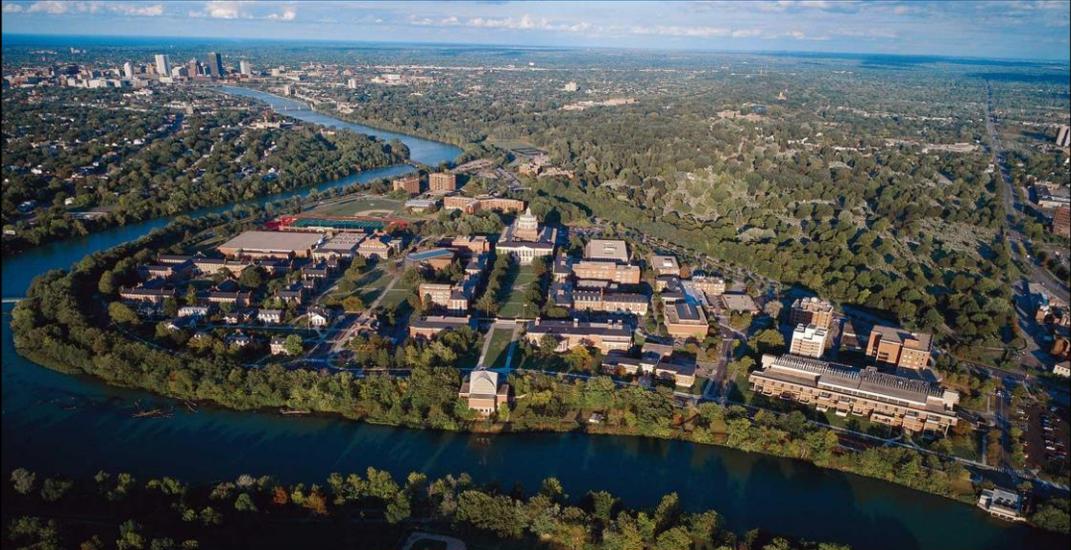
Flowcast; (billing purposes) each procedure is recorded as a different visit



When in doubt...

- **Stop and think**
- **Email the Research Help Desk!**





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